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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,253	07/13/2001	Valerie Wittamer	9409/2042	4887

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EXAMINER	
LI, RUIXIANG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,253	WITTAMER ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to a method of identifying an agent that modulates the function of ChemR23, classified in class 435, subclasses 4 and 7.1.

2. Claim 18, drawn to a method of modulating the activity of a ChemR23 polypeptide in a cell, classified in class 435, subclass 4.

3. Claims 19-21, drawn to a method of diagnosing a disease or disorder characterized by dysregulation of ChemR23 signaling with an antibody, classified in class 435, subclass 7.1.

4. Claims 22-24, 27 (in part), 29 (in part), and 30 (in part), drawn to a method of diagnosing a disease or disorder characterized by dysregulation of ChemR23 signaling by amplifying a ChemR23 polynucleotide, classified in class 435, subclass 6.

5. Claims 25, 26, 27 (in part), 28, 29 (in part), 30 (in part), drawn to a method of diagnosing a disease or disorder characterized by dysregulation of ChemR23 signaling by amplifying a TIG2 polynucleotide, classified in class 435, subclass 6.

6. Claims 31, 34, 35, 39, and 40, drawn to a composition or a kit comprising an isolated ChemR23 polypeptide and an isolated TIG2 polypeptide, classified in class 530, subclass 350.

7. Claim 32, drawn to an antibody specific for a ChemR23 polypeptide, classified in class 530, subclass 387.9.

8. Claim 33, drawn to an antibody specific for a TIG2 polypeptide, classified in class 530, subclass 387.9.
9. Claim 36-38, and 41-43, drawn to a kit comprising an isolated polynucleotide encoding a ChemR23 polypeptide polypeptide and an isolated polynucleotide encoding a TIG2 polypeptide, classified in class 536, subclass 23.5 and class 435, subclass 325.
10. Claim 44, drawn to a non-human mammal having a homozygous null mutation in the gene encoding ChemR23, classified in class 800, subclass 8.
11. Claim 45, drawn to a non-human mammal transgenic for a ChemR23 polynucleotide, classified in class 800, subclass 8.
12. Claim 46, drawn to a non-human mammal transgenic for a TIG2 polynucleotide, classified in class 800, subclass 8.

2. The inventions are distinct, each from the other for the following reasons. Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the different inventions are drawn to completely different methods each having completely different method steps, using different compositions, and having completely different outcomes. Invention I requires identifying an agent that modulates the function of ChemR23; Invention II requires modulating the activity of a ChemR23 polypeptide; Invention III requires diagnosing a disease with an antibody; Invention IV requires diagnosing a disease by amplifying a ChemR23 polynucleotide;

Whereas Invention V requires diagnosing a disease by amplifying a TIG2 polynucleotide. Each method is unique and not required for another. Thus, the methods are exclusive and require non-cohesive searches and considerations.

3. Inventions VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the different inventions are drawn to completely different products, polypeptides, nucleic acid molecules, antibodies, and transgenic animals. These products are not interchangeable and require non-cohesive searches and considerations.
4. Inventions I-V and Inventions VI-XII are either related as product and process of use or are drawn to distinct product and method inventions. In the case that the inventions are related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). For example, a polynucleotides may be used in a materially different process such as production of a polypeptide; a polypeptide may be used in a materially different process such as to immunize mice to produce an antibody; an antibody may be used in a materially different process such as to immunoprecipitate or to purify a polypeptide.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
6. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.
7. Furthermore, the application contains claims which are directed to ChemR23 and TIG2. The specification discloses numerous amino acid/nucleic acid sequences of ChemR23 and TIG2 as represented by different SEQ ID NOS. Each individual sequence represents a structural and functionally distinct entity that is capable of supporting a separate patent. The search and consideration of more than a single sequence constitutes an undue search burden on the office, given the ever-increasing size of the database.

   Applicant is advised that a reply to this requirement must include an identification of an amino acid/ nucleic acid sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. **The Examiner notes that this is not a species election requirement; rather it sets forth additional invention groups.**
8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently

found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871. The fax number for this Group is (703) 872-9306.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Ruixiang Li

Ruixiang Li, Ph.D.
Examiner
June 25, 2004